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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,245

08/18/2003

David R. Fischell

A3-03

2995

7590
Dr. Robert E. Fischell
14600 Viburnum Drive
Dayton, MD 21036

11/28/2007

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/642,245

Applicant(s)

FISCHELL ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 26-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/11/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 1-13 and 26-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/2/06.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, line 1, "the electrogram" lacks antecedent basis. It is suggested to use "an electrogram". In paragraph (c), "of at one beat" should be "of at least one beat". In paragraph (e), line 2, "of at least one sub-segment of at least one beat" should be "of the at least one sub-segment of the at least one beat" since those items have been previously recited.

In claims 15-19 and 21-25, "where" should be "wherein" so that the elements are positively recited since it is unclear if "where" is limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al (6128526). Stadler describes the use of adjusting the start time of the sub-segment in columns 19 and 20. In addition, since he detects myocardial ischemia, he will inherently detect infarction and induced ischemia since they are both ischemias (it is noted that the claims do not state that the detected events are displayed, only detected).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18, 19, and 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stadler et al.

Stadler shows and describes the use of an average isoelectric point 1, the PQ segment (e.g. column 19 and figures 4, 5, etc), for use in analyzing the cardiac event and the use of T wave variation in column 18 for cardiac events.

In the alternative, Stadler discloses the claimed invention except for the averaging of sub-segments, such as the PQ segment, and the use of the T-wave peak as the sub-segment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac event detection system and method as taught by Stadler, with the averaging of sub-segments, such as the PQ segment or ST segment, and the use of the T-wave peak as the sub-segment since it was known in the art that cardiac event detection systems and methods use the averaging of sub-segments, such as the PQ segment, to provide the predictable results of a more stable representation/estimation of the sub-segment and to use conventional cardiac sub-segments, such as the PQ and T wave peak, to provide the predictable results of accurately detecting cardiac events and conditions such as cardiac ischemia and arrhythmias.

Claims 20, 21, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al.

Stadler discloses the claimed invention except for excluding any beats where the R-R interval is shorter than 60 milliseconds, adjusting the start time in proportion to the square root of the R-R interval, and using a look-up table for the start time corresponding to certain values of the R-R interval. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac event detection system and method as taught by Stadler, with excluding any beats where the R-R interval is shorter than 60 milliseconds, adjusting the start time in proportion to the square root of the R-R interval, and using a look-up table for the start time corresponding to certain values of the R-R interval since it was known in the art that cardiac event detection systems and methods use: the excluding of any beats where the R-R interval is shorter than 60 milliseconds to provide the predictable results of preventing

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EMI or noisy beats from providing false indications of cardiac events, such as ischemia; adjusting the start time in proportion to the square root of the R-R interval to provide the predictable results of accurately adjusting the beginning of the sub-segment to reflect the increased/decreased length of the R-R interval using conventional calculations; and using a look-up table for the start time corresponding to certain values of the R-R interval to provide the predictable results of quickly associating the R-R interval with the proper start time without using microprocessor speed and calculation functions. In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cardiac event detection system and method as taught by Stadler with adjusting the start time in proportion to the square root of the R-R interval, because Applicant has not disclosed that adjusting the start time in proportion to the square root of the R-R interval provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with adjusting the start time based on the calculation as taught by Stadler, because it provides the predictable results of accurately moving the start time of the sub-segment based on the heart rate.

Therefore, it would have been an obvious matter of design choice to modify Stadler to obtain the invention as specified in the claim(s).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

11/26/07

GRE
11/26/07